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Participant Information Sheet and Informed Consent
Out-of-hospital LA CAB+RPV. *Version 2.0, June 29, 2023*

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT

STUDY TITLE	" Implementation of the out-of-hospital administration of long-acting Cabotegravir+Rilpivirine as optional therapy in HIV-infected patients in Spain. Acceptability, appropiateness, feasibility, and satisfaction. The HOLA Study. ".
STUDY CODE	Out-of-hospital LA CAB+RPV
PROMOTER	Fundació FLS de Lluita contra la Sida, les Malalties Infectioses i la Promoció de la Salut i La Ciència
PRINCIPAL INVESTIGATOR	
CENTER	

Introduction

We are writing to inform you about a research study in which you are invited to participate, promoted by Fundació FLS de Lluita contra la Sida, les Malalties Infectioses i la Promoció de la Salut i La Ciència. The study has been approved by a Drug Research Ethics Committee and by the Spanish Agency for Medicines and Health Products (AEMPS), in accordance with current legislation, Royal Decree 1090/2015 of December 4 and European Regulation 536/2014 of April 16, which regulates clinical trials with drugs.

Our intention is that you receive the correct and sufficient information so that you can decide whether or not to agree to participate in this study. To do this, read this information sheet carefully and we will clarify any doubts that may arise. In addition, you can consult with the people you consider appropriate.

We invite you to participate in the study because you are diagnosed with HIV, have been prescribed long-acting treatment with Cabotegravir and Rilpivirine and have an undetectable viral load.

The long-acting treatment is a combination of two antiretroviral drugs called Cabotegravir and Rilpivirine. Both act to suppress HIV (human immunodeficiency virus) in a similar way to other antiretrovirals, with the difference that this treatment consists of two injections every two months instead of a daily oral treatment.

Negredo E, *et al. BMJ Open* 2025; 15:e088514. doi: 10.1136/bmjopen-2024-088514

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This treatment is only allowed be administered in the hospital and the aim of this study is to see if the administration of Cabotegravir and Rilpivirine for the treatment of HIV in alternative facilities outside the hospital setting, for example, in primary care centres or in community centres, is acceptable.

Voluntary participation

you should know that your participation in this study is voluntary and that you can choose NOT to participate. If you choose to participate, you can change your decision and withdraw your consent at any time, without altering your relationship with your doctor or harming your health care.

Objective of the study

The main objective of this study is to see if it is acceptable and safe to administer the injections for patients living with HIV that are treated with long-acting Cabotegravir and rilpivirine intramuscularly every 2 months outside the hospital.

The findings of this study will help us understand how the administration of the drugs outside of a hospital setting can be implemented and to see if it is acceptable, appropriate, feasible and satisfactory to administer Cabotegravir and Rilpivirine injections every 2 months in primary care centers or in community centers, as well as to evaluate the safety of the administration of Cabotegravir and Rilpivirine injections.

Study Description

This study will involve 110 adults living with HIV who have controlled disease (undetectable viral load) with their current HIV medication.

The medications that will be administered are injections of Cabotegravir and Rilpivirine. Participants will be divided into two groups:

- Group I: You will be given the dose of Cabotegravir and Rilpivirine in the hospital
- Group II: You will be given the dose of Cabotegravir and Rilpivirine outside the hospital, in a community center, or in a primary care center already assigned by the study.

Neither do you nor will the researcher know which group will be assigned before being included in the study. It will be decided at random (like flipping a coin) to which group you will belong. This is done to get reliable data from the results of the study.

Every 2 months you will receive 2 injections; each contains one of the two drugs that make up the treatment. You will be given an injection on each side of the upper outer part of the gluteus.

These medicines are approved by the AEMPS under the name Vocabria® (Cabotegravir) and Rekambys® (Rilpivirine).

If you have not been given Cabotegravir and Rilpivirine injections before, you will take the same oral medication for 28 days and, on the last day of oral medication, you will receive the first dose of Cabotegravir and Rilpivirine in the hospital. From the following month, the injections of Cabotegravir and Rilpivirine will be administered every 2 months at the center where you have been randomly assigned.

These oral medications are also approved by the AEMPS. In Spain, Rilpivirine is marketed under the name Edurant® and Cabotegravir under the name Vocabria®. The aim of this first phase of oral treatment is to ensure tolerance of the drugs.

Study activities

The study will last 12 months of treatment, in which 7 face-to-face visits will be carried out.

In the case of patients who have not previously been administered intramuscular cabotegravir and rilpivirine, they should make an additional visit after 28 days of oral antiretroviral treatment, to confirm good tolerance to the treatment.

Before starting the study:

Selection/baseline visit:

If you decide to participate in the study, we will ask you to sign this **informed consent before** you are enrolled, we will ask you some questions, and we will collect some data to confirm that you meet all the selection criteria to participate in the study. On this visit we will do:

- A review of your medical history
- A physical exam
- A review of your medication
- A test with determination of HIV viral load
- A pregnancy test

- Questionnaires

During the study: *Study visits:*

Visits will be made every 2 months in which you will be given injections of Cabotegravir and Rilpivirine and questionnaires will be completed during the visits to assess whether the treatment is acceptable, appropriate and feasible, as well as your degree of satisfaction and expectations of the treatment and a questionnaire that will measure the perception of the injection, which you will have to fill out two days after the administrations.

A visit will be made in month 1 in the hospital if it is the first time that the medication Cabotegravir and intramuscular Rilpivirine is administered. At this visit, a blood draw will be performed for the determination of the HIV viral load, and the questionnaires will be completed. A questionnaire that will measure the perception of the injection will have to be filled in two days after the administration.

At the 6th month and 12th month visits, you will go to the hospital where you will have a blood draw to determine the HIV viral load and other tests, similar to those carried out for the monitoring of HIV infection in routine clinical practice (blood count, basic biochemistry and CD4/CD8 lymphocyte count).

In the visits of month 2, month 4, month 8 and month 10, only the questionnaire that will measure the perception of the injection will be completed, which will have to be filled out two days after the administration.

Procedure	Selection/Basal	Month 1	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12
Informed Consent	X							
Clinic Visit (Medical History/Physical Exam)	X	X			X			X
Blood Draw	X	X			X			X

Pregnancy test (if applicable)	X	X			X			X
Study Questionnaires	X	X			X			X
Injection Perception Questionnaire		X	X	X	X	X	X	X
Oral Administration of Cabotegravir and Rilpivirine	X							
Intramuscular Administration of Cabotegravir and Rilpivirine		X	X	X	X	X	X	X

Blood Sample Collection:

Blood drawings will be routinary and will be carried out by the nursing staff of the HIV Unit of your Hospital. The amount of blood that will be drawn at each of the study visits will be approximately 30 mL.

Risks and discomforts arising from your participation in the study

In previous trials of Cabotegravir and rilpivirine it well tolerated, and serious adverse reactions were very rare.

The adverse reactions described are:

Frequency	Adverse Effect
Very common (at least 1 in 10 people)	Headache
	Injection site reactions. They are usually mild to moderate and their frequency decreases over time. Symptoms may include:- Very common: pain and discomfort, hard lumps or masses- Common: redness, itching, swelling, warmth, or bruising (which may include a change in color or a collection of blood under the skin).- Uncommon: numbness, light bleeding, abscess formation (accumulation of pus) or cellulitis (with a feeling of warmth, swelling, or redness).
	Feeling warm (pyrexia), which may occur in the first week after injections
Common (affects less	Depression
	Anxiety
	Abnormal dreams

than 1 in 10 people)	Difficulty sleeping (insomnia)
	Dizziness
	Feeling unwell (nausea)
	Vomiting
	Abdominal pain
	Gases
	Diarrhoea
	Rash
	Muscle pain
	Tiredness (fatigue)
	Feeling weak (asthenia)
	Malaise
	Weight gain
Rare (affects less than 1 in 100 people)	Numbness (drowsiness)
	Feeling dizzy during or after an injection. This can lead to fainting.
	Liver damage (signs may include yellowing of the skin and whites of the eye, loss of appetite, itching, tenderness of the belly, light-colored stools, or abnormally dark urine).
	Changes in laboratory levels of liver function (increased transaminases)
	Increased bilirubin (a substance produced by the liver) in the blood.

Injection site reactions

You may experience local reactions at the site where you received the injections. Very common side effects can include pain or discomfort, which is usually mild or moderate. You may also have redness, swelling, itching, bruising, lumps, complications such as infection (cellulitis or abscess), and irritation where the injection(s) are given. In most cases, the reactions are mild (75%), while 4% of participants in previous clinical trials had a severe reaction at the injection site. Most reactions go away in a week or less, but sometimes they can last a long time. Most people find these reactions acceptable and rarely stop the injections due to adverse effects.

Possible side effects of the injection procedure

Symptoms of the post-injection reaction have occurred in some people within a few minutes of receiving the rilpivirine injection. Post-injection reactions are rare and occurred in less than 0.5% of participants in clinical trials. Most symptoms resolved within a few minutes of the injection. Symptoms of post-injection reactions may include: shortness of breath, stomach cramps, rash,

sweating, numbness in the mouth, anxious feeling, feeling warm, feeling dizzy or light-headed, changes in blood pressure, and back and/or chest pain. Tell your study doctor if you experience these symptoms after receiving the injections. These cases may be due to an accidental injection of part of the medication into a blood vessel instead of the muscle. Not all patients in whom accidental injection into a blood vessel was suspected reported such symptoms. Most symptoms resolved within minutes. Your doctor may need to give treatment to help resolve these symptoms. The study health care staff will observe you briefly (about 10 minutes) after the injection.

The injections will be given into the muscles of the buttocks. The injection may not reach the muscle or be given too far, not reaching the muscle and penetrating the skin, blood vessels, or nerves. The consequences of this are not well understood, but it could cause the levels of Cabotegravir and Rilpivirine to be too low or high. If they are too low, the medicine may not work properly against HIV. If the levels of Rilpivirine are too high, your heart rate could be altered, which very rarely, in severe cases, can be life-threatening and lead to sudden death; however, to date, no such severe changes in heart rate or sudden deaths have been observed in clinical studies with rilpivirine in any of its forms of administration (oral or intramuscular). Every effort will be made to decrease this risk, including ensuring that the correct size needle and proper injection technique are used. The staff is trained for it. You will also be monitored after each injection and during the test, as appropriate. If your doctor thinks the injection was not given correctly, you may be asked to stay at the center for up to 2 hours after the injection to monitor your progress, and additional tests may be needed to make sure there are no risks. If you are concerned about this issue, talk to your study doctor.

Hypersensitivity

Hypersensitivity reactions (also known as allergic reactions) have been reported with other medicines in the same class as Cabotegravir, with signs and symptoms of general feeling of malaise, rash, high fever, lack of energy, swelling (sometimes of the face or mouth, causing difficulty breathing), blisters, mouth ulcers, conjunctivitis, and muscle or joint aches. If you develop any of these signs and/or symptoms during the study, you should immediately call the study team to decide if any testing is required and/or to tell them to stop taking Cabotegravir and Rilpivirine. If you are told to stop taking your medications, you should do so immediately.

Rash

Treatment with Cabotegravir and rilpivirine may cause a rash. Most are mild or moderate, but some types can be severe and treatment will need to be stopped. If you have any type of rash, itching, or other skin problems during treatment, you should tell the study team right away. You may be asked to come in for a scan, analysis, and/or tell you to stop taking Cabotegravir and/or Rilpivirine.

Impaired liver tests

A small number of participants in research studies who took Cabotegravir with rilpivirine developed impaired liver tests that forced them to stop treatment. In some cases, abnormal liver tests were explained by other causes (e.g., a new infection with a virus), while a smaller number (less than 1% of participants) had no alternative explanations, suggesting a mild form of liver damage suspected to be due to Cabotegravir and/or Rilpivirine. Liver tests improved after stopping the medication, suggesting that any possible damage was temporary. Blood tests will be carried out to check the health of the liver during this study, as part of your routine check-ups and you will be informed if any alterations occur and, if so, the steps to follow. If a liver problem occurs, you may be asked to stop taking the study treatment.

What if the side effects are intolerable?

If you experience side effects that are intolerable and need to change your HIV medications, you will need to stop the study**.**

What other possible risks are there?

Risk of HIV becoming resistant to treatment

With any drug used to treat HIV, there is a risk that the virus will become drug resistant, which means that the drug will lose its activity. The risk of developing resistance will depend on whether the treatment manages to keep the viral load undetectable, and this, in turn, will depend on you following the instructions on how to take the study medicines.

Therefore, it is very important that you attend your study visits on your scheduled dates and that you always take your treatment exactly as prescribed. Talk to your study doctor each time you stop

taking any tablets or if you think you will need to delay or advance your visits to receive injections due to work, vacation, travel, etc., that may interfere with your scheduled visits.

If you need to delay injections for more than a few days, you may be offered the option to take tablets for a short period of time, which is known as an 'oral bridge'. Your study doctor will be able to advise you on whether this is right for you.

Do not change or skip any doses of any of the study drugs unless your study doctor tells you to. Missing doses of medication (tablets or an injection) can lead to HIV becoming resistant to the drugs and these not working. This could also limit the possibilities of using other HIV medicines related to drug resistance in the future.
On the other hand, if stopping the long-acting treatment, it is important to start taking another HIV medication, as recommended by your study doctor, to maintain HIV control and prevent acquiring drug resistance.

Side effects after receiving long-acting injections

After an injection of Cabotegravir and Rilpivirine, these drugs will stay in your body for a long time. In some people, low levels of Cabotegravir and Rilpivirine may be present in the body for more than a year after the last injection. If you develop a side effect of the study drug after an injection, there will be no way to remove the drug from your body. If this happens, your doctor will do everything possible to treat the symptoms.
When you stop long-acting injections, the amount of medication in your body will decrease over time and go away.

Feeling faint after the injection

When receiving the injections, some people may feel dizzy or like they might pass out. This reaction, also called a "vasovagal reaction," may occur with many medical procedures, however resolves quickly, and is not a threat to your health.

Blood draw

When your blood is drawn, you may feel dizzy or experience mild pain, bruising, irritation, or redness at the puncture site. In rare cases, you can get an infection.

Mental health issues

Some people with chronic health problems, including HIV, sometimes have feelings of depression or may have thoughts of harming themselves or taking their own life (suicide). A small number of people taking Cabotegravir and Rilpivirine have had suicidal thoughts and actions, particularly those with a history of depression or mental health problems.

Tell the study doctor if you have a history of mental health problems. If you have thoughts of self-harm or suicide or have other unusual or uncomfortable thoughts or feelings during this study, you should tell the study doctor or go to the nearest hospital right away.

This list of side effects is not complete. You may experience side effects that are different from those described in this informed consent form or that are not currently known.

Medication NOT allowed during the study

The use of some other drugs is contraindicated or should be done with caution when administered concomitantly with Cabotegravir and/or Rilpivirine. For this reason, the following drugs are not allowed to be used during the study:

- Carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines to treat epilepsy and prevent seizures)
- Rifabutin, rifampicin, rifapentine (medicines to treat bacterial infections such as tuberculosis)
- Dexamethasone (a corticosteroid used to treat a variety of conditions, such as inflammation and allergic reactions) given in an oral or injectable course of treatment
- Products that contain St. John's wort or St. John's wort (Hypericum perforatum, a medicinal plant used for depression).

Do not use medications (prescription and over-the-counter) without first talking to the study medical staff. The study medical staff will explain the need to avoid certain medications during the study, including those that are contraindicated. New drugs may be identified later that need to be added to the list of drugs you should not take during the study.

Can a pregnant person participate in the study?

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Because there is no information available about the safety of long-acting cabotegravir and rilpivirine for the fetus, pregnant people are not allowed to participate in the study.

For this reason, as part of the tests planned at the screening visit and at the study visits, urine pregnancy tests will be performed on all menstruating people of childbearing potential* who wish to participate in the study or have been included in the study. The result must be confirmed as negative prior to administration of the first dose of study drugs. Pregnancy tests will also be done at any time during the study when pregnancy is suspected.

If you are a person who is able to have children, you should use birth control while participating in the study. Effective birth control should be used, as agreed with your study doctor, from at least 14 days prior to the start of your first dose of Cabotegravir and Rilpivirine and for as long as you are taking the study medication. It is recommended that you continue to use effective contraception until at least 14 days after your last oral dose of Cabotegravir and Rilpivirine, and at least 13 months after your last long-acting injection(s), as the study drugs may still be present in the body during this time. Your study doctor will talk with you about this recommendation and the potential risks of pregnancy during this time. You should tell your primary care physician and your HIV Unit doctor if you have a pregnancy within 12 months of the last Cabotegravir and Rilpivirine injection even if you are no longer in the study.

Therefore, at the screening visit and during the study, the use of one of the following contraceptive methods considered highly effective in preventing pregnancy should be accepted:

- hormonal contraception or intrauterine device [IUD]
- one's own or the partner's anatomical sterility

If the pregnancy test result is positive or equivocal, intramuscular injections should be postponed until a valid serum pregnancy test is obtained. If the test is positive, you will stop taking the study medication and the medical staff responsible for the study will inform you about the next actions to take (see next section).

What will happen if a person becomes pregnant during the study?

You should inform the study research team immediately if you suspect that there is a possibility of pregnancy during the study. If their participation in the study has ended, they should inform their usual doctor during HIV follow-up.

If your pregnancy is confirmed during the study, you will be given the option to switch to alternative antiretroviral therapy during pregnancy. An alternative antiretroviral treatment that is considered suitable for use during pregnancy will be initiated in accordance with local guidelines. The deadline for starting this treatment will be the expected date for the next injection of Cabotegravir and Rilpivirine.

After the study

When your participation ends, you will receive the best available treatment, the one that your doctor considers most appropriate for your disease, at your hospital. Because the study medication will already be marketed, you may still be able to be given the study medication, but neither the investigator nor the sponsor makes any commitment to maintain the treatment outside of this study.

What are the expected benefits of this study?

Possible benefits:

By participating in this study, you will receive antiretroviral treatment that has been shown to be highly effective and tolerable in different clinical trials. It is hoped that this study will be able to analyze whether the administration of the treatment is acceptable, appropriate and feasible to carry out outside the hospital setting and can be implemented in primary care centers and community centers, which may benefit other people infected with HIV in the future.

Costs:

You will not have to pay for medications or specific tests from the study. Your participation in the study will not incur any additional costs to your usual clinical practice. The study will be funded by the pharmaceutical company ViiV Healthcare in collaboration with Lluita Foundation against AIDS and Infectious Diseases.

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Confidentiality and legal information

The sponsor of the study and the participating centres, as independent data controllers, will guarantee the confidentiality of the personal information of the participating subjects in accordance with current legal regulations (Organic Law 3/2018, on the Protection of Personal Data and Guarantee of Digital Rights, and Regulation [EU] 2016/679 of the European Parliament and of the Council, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data). During this study, the study medical team will record information about you, your health, and your participation in the study on forms called data collection notebooks.

To ensure that the data collected during the study are treated confidentially, your data will be identified by a code; your name or any other information that allows you to be directly identified will not be included in the data collection notebooks. Therefore, the identity will not be revealed to any other person except to the health authorities, when required or in cases of medical emergency. The ethics committees, the representatives of the Health Authority in matters of inspection and the personnel authorised by the sponsor may only access to check the personal data, the procedures of the clinical study and compliance with the rules of good clinical practice (always maintaining the confidentiality of the information).

Only the study medical staff/collaborators will be able to relate this data to you and your medical history. The sponsor will only have access to information relating to the general results of the study. Under no circumstances will you access your personal data.

To carry out this clinical trial, we will also need access to the medical information contained in your medical record and we will record your participation and safety aspects throughout the study in the electronic medical record system of the participating centers, so you must expressly authorize us to do so.

The data controllers are the sponsor, the Lluita Foundation against AIDS and Infectious Diseases, as well as the centres where this study will be carried out, belonging to the Catalan Health Institute and the Regional Government of Andalusia

- Data Protection Officer within the scope of the Department of Health contact email: [redacted]

- Data Protection Officer in the field of the Junta de Andalucía contact email [redacted]
- Data Protection Officer of Fundació FLS de Lluita contra la Sida, les Malalties Infectioses i la Promoció de la Salut i La Ciència (developer), with address Ctra. de Canyet s/n, Hosp. Univ. Germans Trias i Pujol, 2a planta Maternal, 08916 Badalona (Barcelona): [redacted]

Legal basis for data processing: The consent granted by means of this document and the general interest in the treatment of the disease.

Recipients: The recipients of the data are the research team and the personnel authorised by the data controllers, the suppliers that are necessary for the purpose of the processing (laboratories, software and hosting provider companies) and, where appropriate, the relevant administrative authorities. Although the data will be kept pseudonymized during the study, we inform you that your information will be hosted on a secure server located in the European Union under current regulations with the highest quality and specific security. The encrypted data may be transmitted to third parties and other countries, but in no case will it contain information that can identify you directly or indirectly, and contracts will be established with the recipients of the information that expressly prohibit re-identification, by cross-referencing with other databases or any technology that attempts to re-identify the data. In the event that this transfer occurs, it will be for the same purposes as the study described or for use in scientific publications, but always maintaining the confidentiality of these, in accordance with current legislation.

Rights: You can exercise your rights of access, rectification, cancellation, opposition, limitation of the processing of data that are incorrect, request a copy or that they be transferred to a third party (portability) of the patient on the data you have provided for the study (PARSOL Rights). To exercise their rights, the participant may contact the team of researchers or the data protection officer of the institutions

Data retention: The sponsor will retain records of the clinical trial for a period of at least 25 years after completion. Thereafter, your personal information will only be retained by your health care facility. The promoter will keep data that at no time will contain personal data.

We remind you that the data cannot be deleted, even if you stop participating in the study, to ensure the validity of the research and comply with legal duties and drug authorization

requirements. Therefore, if you decide to withdraw consent to participate in this study, no new data will be added to the database, but any data that has already been collected will be used.

Right to complain: You can exercise your right to lodge a complaint with the competent authority (the Catalan Data Protection Authority or the Spanish Data Protection Authority), if you consider that your data protection rights have been violated.

Sure:

The promoter of the study has taken out a civil liability insurance policy with the company Zurich Insurance PLC branch in Spain in accordance with the requirements established in RD 1090/2015, which covers the possible damages that they may experience as a result of their participation in the trial, provided that they are not a consequence of the disease under study itself or of the evolution of their disease as a result of the ineffectiveness of the treatment.

It is also possible that your participation in this clinical trial may modify the general and particular conditions (coverage) of your insurance policies (life, health, accident) and, therefore, we recommend that you contact your insurance company and inform them of your participation in it to determine if it could affect your current insurance policy or in the event that you are going to take out a new policy.

For more information regarding this section, please consult with the principal investigator of the study at your center.

Study Participation:

You do not need to make the decision at this time to participate in this study, you can take this Information Sheet home and think about it long enough and discuss your participation with your family or regular doctor.

You participate in this study on a voluntary basis and may withdraw from the study at any time without having to explain yourself or your subsequent attendance at our Consultation being affected.

Once the Informed Consent is signed, you will keep a copy of this document.

There is the possibility of exclusion from the trial by the sponsor or the research team, in the event of safety problems or non-compliance with the procedures established in the study.

In the event of cancellation of the trial by the sponsor, the participants will be informed of the reasons.

Any new information regarding the drugs used in the study that may affect your decision to continue in the study will be communicated to you by your doctor as soon as possible and, if necessary, a new consent will be signed.

Contact for information

If you have any questions or problems related to your infection or the treatment given, outside of working hours, you can contact the principal investigator of the study:

Dr/a.....

Tel.....

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PRINCIPAL INVESTIGATOR	
CENTER	

I, (name and surname)....., after having read the information sheet that has been given to me and asking the clarifying questions about it to Dr./Dr.....

I confirm that I have received enough information about the study and that I have understood the objectives of the study and what it entails.

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

- Whenever.
- Without having to give explanations.
- Without this having an impact on my medical care.

And I consent:

- That the clinical data collected during the study be stored in an automated file whose information may be handled exclusively for scientific purposes, provided that the information concerning me is dissociated (this means that the information obtained cannot be related to the person from whom it comes).
- I understand that I have the possibility of exercising the rights of access, rectification, cancellation, opposition, limitation of processing, data portability and not to be subject to automatic individualized decisions (profiling), by writing to the Data Protection Officer

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within the scope of the Department of Health [redacted] Junta de Andalucía [redacted], or the promoter [redacted]

I agree with everything related to this study and freely agree to participate in it and that my data can be used for research purposes as stated in the patient information sheet.

Patient signature Signature of the Researcher

Date Date

You will receive a copy of this document, once you have signed it, to keep with your records.

FOR ADULTS WHO ARE UNABLE TO GIVE CONSENT

……,
Witness/interpreter at the consent interview

As of the date signed, I have been a witness in the consent interview for the research study named at the beginning of this document. I confirm that the information contained in this consent form was properly explained to the subject, and the subject has confirmed that all of their questions have been adequately answered.

Name of witness
Signature of the witness Signature of the Researcher

Date Date

The study subject will receive a completed fact sheet, along with a signed version of the consent form